

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in December 2001.

New Approvals

ANADA Number: 200-318

Pioneer Product: 140-841
Trade Name: Virbamec™ Pour-On
Ingredients: Ivermectin
Sponsor: Virbac AH, Inc.
Approval Date: September 21, 2001
Status: Over-the-counter
Route: Topical
Species: Cattle
Drug Form: Liquid (solution)
Concentration: 5 milligrams per milliliter
Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, chorioptic and sarcoptic mange mites. Treatment for horn flies for 28 days. It is also use to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.
Tolerance: 21CFR 556.344 Ivermectin: A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) as 100 parts per billion (ppb) in liver and 10 ppb in muscle.
Withdrawal: 48 days (withdrawal time in milk has not been established).

21CFR 524.1193 and 510.600

ANADA Number: 200-321

Pioneer Product: 140-439
Trade Name: Primectin™ Equine Oral Liquid
Ingredients: Ivermectin
Sponsor: First Priority, Inc.
Approval Date: September 7, 2001
Status: Prescription only
Route: Oral
Species: Horses
Drug Form: Liquid (solution)
Concentration: 10 milligrams per milliliter
Indications: For treatment of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

21CFR 520.1195

Actions Taken by FDA Center for Veterinary Medicine

Supplemental Approvals

NADA Number: 140-951

This supplemental application provides for use of approved diclazuril Type A Medicated Article to make Type B and Type C medicated feeds in growing turkeys. Also tolerances for diclazuril residues in turkey are being established.

Trade Name: ClinacoxTM
Ingredients: Diclazuril
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: September 21, 2001
Status: Over-the-counter
Route: Oral
Species: Growing turkeys and broiler chickens
Drug Form: Type A Medicated Article to make Type B and Type C medicated feeds.
Concentration: 0.2%
Indications: Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. gallopavonis*, and *E. meleagrimitis*.
Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, and *E. mitis (mivati)*. Also for the control of coccidiosis caused by *E. maxima*.
Tolerance: 21CFR 556.185 Diclazuril: (1) Turkeys: Tolerances are established for residues of parent diclazuril at 0.5 part per million (ppm) in muscle, 3 ppm in liver, and 1 ppm in skin/fat.
(2) Chickens: Tolerances are established for residues of parent diclazuril at 0.5 ppm in muscle, 3 ppm in liver, and 1 ppm in skin/fat.
The acceptable daily intake for total residues is 25 micrograms per kilogram of body weight per day.
Withdrawal: Zero days
Patent Number: 4,631,278 Expiration Date: August 1, 2004
Exclusivity: 3 years

21CFR 556.185 and 558.198

NADA Number: 141-053

This supplemental application provides for a once a day dose of carprofen for the relief of pain and inflammation associated with osteoarthritis.

Trade Name: Rimadyl Caplets
Ingredients: Carprofen
Sponsor: Pfizer, Inc.
Approval Date: September 27, 2001
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablet (caplet)
Concentration: 25, 75, or 100 milligrams per tablet
Indications: For the relief of pain and inflammation associated with osteoarthritis in dogs.
Patent Numbers: 4,264,500 Expiration Date: February 28, 2003
6,013,808 April 15, 2019
Exclusivity: 3 years

21CFR 520.309

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 115-581

This supplemental application provides for the addition of the claim for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* to MoorMan's Type C medicated free-choice protein-mineral blocks.

Trade Name: Moorman's® Mintrate® Blonde Block, Moorman's® Mintrate® Red Block RU
Ingredients: Monensin Sodium
Sponsor: MoorMan's, Inc.
Approval Date: September 27, 2001
Status: Over-the-counter
Route: Oral
Species: Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).
Drug Form: Type A Medicated Article to make Type C medicated feed.
Concentration: 80 grams of monensin activity per pound of Type A Medicated Article.
Indications: For increased rate of weight gain, prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.
Tolerance: 21CFR 556.420 Monensin: A tolerance of 0.05 ppm is established for negligible residues of monensin in edible tissues of cattle.
Withdrawal: Zero days

21CFR 558.355

Addition of Sponsor

Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137
Drug Labeler Code: 051311

Change of Sponsor's Address

From: Merial Ltd.
2100 Ronson Rd.
Iselin, NJ 08830-3077

To: Merial Ltd.
3239 Satellite Blvd., Bldg. 500
Duluth, GA 30096-4640
Drug Labeler Code: 050604

From: Phibro Animal Health
One Parker Plaza
Fort Lee, NJ 07024

To: Phibro Animal Health
710 Rt. 46 East, Suite 401
Fairfield, NJ 07004
Drug Labeler Code: 066104

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor

NADA Numbers: 009-476, 098-378, 107-997, 108-115, 108-116, 141-146

From: Koffolk, Inc.
To: Phibro Animal Health, Inc.
710 Rte. 46 East, Suite 401
Fairfield, NJ 07004
Drug labeler code: 066104

Suitability Petition Action

Number: 01P-0139/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab[®], Lloyd, Inc., NADA 140-921, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Approved on December 19, 2001.

Number: 01P-0140/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, cefadroxil, which differs from the pioneer product, Cefa-Drops[®], Fort Dodge Animal Health, Division of AHP, NADA 140-684, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Approved on December 19, 2001.

Number: 01P-0141/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Amoxi-Drop[®], Pfizer Inc., NADA 055-085, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Approved on December 19, 2001.